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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815

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EXAMINER	
CRANDALL, LYNSEY P	
ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
01/12/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/776,688	ALTSHULER ET AL.	
	Examiner	Art Unit	
	LYNSEY CRANDALL	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,9,15-17,19,23,24,26,28-30 and 48-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/31/2009-1; 12/31/2009-2; 12/31/2009-3; 12/31/2009-4; 12/31/2009-5; 12/31/2009-6; 12/31/2009-7; 12/31/2009-8; 12/31/2009-9; 12/31/2009-10; 12/31/2009-11.

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 10/14/2009, with respect to the rejection(s) of claim(s) 78-95 under 102(b) and 53-56, 74-77 and 96 under 103(a) have been fully considered and are persuasive. Applicant's arguments that Biel does not disclose irradiating with two wavelengths concurrently is found convincing. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a newly found prior art reference.

2. With regards to the election by original presentation, applicant's arguments are considered persuasive, therefore claims 1, 5-6, 9, 15-17, 19, 23-24, 26, 29-30, 48-49, 50-52, 57-73 and 97-104 will be examined.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 10/680,705 and 10/702,104, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. These prior-filed applications fail to disclose treating the oral cavity, which is the basis for all the claims in the current application.

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 53-56 and 74-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The currently claimed power density range of 1 W/cm^2 to about 10 W/cm^2 is considered new matter. Applicant cites

paragraph [0015] for support of this amendment. This paragraph reads "a range of about 10 Joules/cm^2 to about 100 Joules/cm^2, in the irradiated tissue. The treatment sessions, each of which last for about 10 seconds to about 1000 seconds." Clearly, the claimed power density ranges are not explicitly disclosed here, in fact in the same paragraph [0015] applicant discloses a range of 1 mW/cm^2 to about 10 W/cm^2. Applicant goes on to state that for a disclosed treatment time of 10 seconds, arbitrarily chosen from a treatment time in the range of 10 seconds to 1000 seconds, the resulting power density would be the claimed range of 1 W/cm^2 to about 10 W/cm^2. Randomly choosing a disclosed treatment time from a range of treatment times to provide a specific power density range is considered new matter. For instance, if applicant were to choose 1000 seconds, also a disclosed treatment time, the resulting power density range would be 10 mW/cm^2 to 100 mW/cm^2. The currently claimed range is not explicitly disclosed, and applicant gives no importance or criticality to the specific power density. Amending a range to distinguish over a prior art reference is considered new matter if that range is not explicitly disclosed. Based on applicant's arguments, hundreds of power density ranges could be formulated by arbitrarily choosing a treatment time disclosed, none of which are given any criticality. If applicant amends claims to include a specific range from a disclosure of a broad range in order to overcome a prior art rejection, this is considered new matter (MPEP 2163.05).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 5-6, 9, 15-17, 19, 23, 24, 26, 28-30, 48-52, 57-73 and 78-104 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,443,978 to Zharov.

8. Zharov discloses a light therapy device used to treat various extensive pathologies on the patient including dermatology, cosmetology, treatment of traumas, bruises, blood therapy and treatment of infectious processes (abstract). Zharov discloses a device (15, Fig. 2 and 2A) that is placed in the oral cavity of a patient and irradiated with diodes (1, Fig. 2A). The device includes a plurality of radiation sources emitting radiation at one or more wavelengths in the range from ultraviolet to radio (claim 1), specifically 630 nm to 800 nm, having a power density of up to 200 mW/cm^2 (Col 4, lines 10-14) and a treatment time from 10 minutes to 50 minutes (claim 64). Zharov discloses multiple treatment sessions, specifically six procedures lasting 15 minutes each within one week (Col 12, lines 8-10).

9. Zharov discloses a power density of 2 mW/cm^2 to 200 mW/cm^2 and a treatment time from 10 minutes to 50 minutes (claim 64). Using a power density of 2 mW/cm^2 (.002 W/cm^2) and a treatment time of 10 minutes (600 seconds), results in an energy flux of 1.2 Joules/cm^2 (.002 W/cm^2 * 600 seconds). Similarly, Using a power density of 20 mW/cm^2 (.02 W/cm^2) and a treatment time of 10 minutes (600 seconds), results in an energy flux of 12 Joules/cm^2 (.02 W/cm^2 * 600 seconds). Zharov discloses using diodes

having a power of 0.5 to 5 Watts (Col 4, 35-37). Zharov discloses using infrared radiation in addition to visible radiation in order to heat tissue (Col 4, lines 35-41). Zharov discloses biological sensors to allow feedback and monitoring of the treatment (Col 2, lines 44-51).

10. Wavelengths of the sources are chosen on the basis of the absorption wavelengths of biomolecules of both exogenous and endogenous origins (Col 2, lines 4-7); these endogenous biomolecules are interpreted as light acceptors. The type or location of the light acceptors does not affect the claimed method steps of irradiating the oral cavity. Zharov discloses irradiating the oral cavity with similar wavelengths, power density, treatment time and energy flux. Inherently Zharov's method irradiates the blood and deposits a dose of radiation below an area of facial skin. Since these light acceptors exist naturally within the blood in the oral cavity, Zharov's method would target them as well. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex Parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993). For example, Zharov's method inherently produces a dermatological or cosmetic result.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 53-56 and 74-77 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,443,978 to Zharov and further in view of U.S. 2003/0009158 to Perricone.

14. Zharov is discussed above, but is silent with regards to a specific power density. Perricone discloses a dermatological or cosmetic treatment of the mouth region (Par 0015 and abstract) using light having a power density of more than 800 mW/cm^2 (Par 0019 and Claim 3). It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use the power density disclosed by Perricone in the method taught by Zharov as it is an effective power density for dermatologically treating the mouth region of a patient.

Allowable Subject Matter

15. Claim 18 is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNSEY CRANDALL whose telephone number is (571)270-7035. The examiner can normally be reached on Monday to Thursday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hank Johnson can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYNSEY CRANDALL/
Examiner, Art Unit 3769

12/31/2009

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769